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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,103

10/27/2003

James F. Zucherman

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COATS & BENNETT/MEDTRONIC
1400 CRESCENT GREEN
SUITE 300
CARY, NC 27518

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,103	Applicant(s) ZUCHERMAN ET AL.	
	Examiner JAMES L. SWIGER III	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 43-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 and 43-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/27/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

There is no claim 42. This is an incomplete listing of claims. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1, 3-4, 6-10, 12, 14-20, 23, 26-27, 29-31, 33-36, 62, 64-67** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128).

Zucherman et al. disclose an implant capable of being placed between spinous processes having a body (902), a spacer (1016) capable of rotation on a shaft. Note that spokes 1020 do not necessarily *prevent* rotation, but merely help the spacer to fit better (See Col. 23, lines 15-37). Zucherman et al. also disclose a tissue expander (1010) extending from the shaft. Zucherman et al. also disclose a spacer that has a cross-sectional shape that may be considered oval-shaped (see Fig. 93a), has a dimension that could be 8 or 10mm (see table in Column 20), and wherein the tissue

Art Unit: 3775

expander has a generally increasing cross section as it approaches wing 1032. The spacer is also connected at an attachment (1014) and the attachment includes a device for receiving a wing (1034), and a first wing (1032). The shaft includes an attachment to which the tissue expander is molded (see Fig. 92a). The spacer (1016) is located between a first wing (1032) and a second wing (1004), and see Fig. 92b. Zucherman et al. also disclose an outer spacer (1016) and an inner spacer (1002) capable of being rotatable with one another, as noted above. Also the spacers' structure may be considered have flattened or slightly radiused upper and lower surfaces (see profile in Fig. 93a), and rounded edges.

Zucherman et al. disclose the claimed invention except for a tissue expander being radiolucent. Brantigan '757 teaches the incorporation of radiolucent material for improved X-ray visualization of the device (see col. 1, lines 31-36). The spacer is also capable of being at least partially radiolucent, and would allow a T-shape combined with a radiopaque wing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zucherman et al. '342 having at least a partially radiolucent portion in view of Brantigan '757 to better allow the device to be seen during surgery in the presence of X-ray.

The combination of Zucherman '342 and Brantigan '757 disclose the claimed invention except for a portion that is at least partially radiopaque. Branch et al. '592 disclose a fusion device that is at least partially radiopaque that allows a means for viewing placement of the implant via radiography during surgery. (See par 0009). It would have been obvious to one having ordinary skill in the art at the time the invention

Art Unit: 3775

was made to construct the device of the combination of Zucherman et al. '342 and Brantigan '757 having at least a portion radiopaque in view of Branch '592 to allow the device to be better viewed in surgery.

The combination of Zucherman et al. '342 and Brantigan '757 and Branch '592 (hereafter "ZBB") disclose the claimed invention. However, it is further noted that the claims are further rejected in view of Carter OR Crickenberger et al. ZBB disclose the claimed invention except for specifically pointing out where the implant is made of a combination of materials. It is noted that use of radiopaque and radiolucent materials is well known in the art for providing improved visualization when doing surgery in combination with some form of imaging or fluoroscopic technique. Carter discloses an implant. The implant is mostly radiolucent, but to help in visualizing the location of the implant, a radiopaque identification marker is placed within it. (see Abstract for quick reference) Use of BOTH materials is known in the art to assist in visualizing the implant during surgery. Regarding Crickenberger et al., Crickenberger teaches an implant (13) having a stem which is radiolucent which further has a radiopaque angle locator wire located within it. Both materials are disposed together to assist in visualization during surgery. See Abstract for quick reference. It is further noted that in a patent to Arroyo (US Patent 4,837,279), Arroyo teaches a bone cement or implant. Arroyo also teaches that polymers are known in the art to be radiolucent--similarly to applicant's claimed invention. However, since it is hard to see a radiolucent material, "opacifiers" or radiopaque materials are added to the cement or implant to help identify its location or placement. (See also Col. 1, lines 28-42). In a similar way, it would be obvious to

Art Unit: 3775

combine both radiopaque or radiolucent materials to help assist with visualization of an implant during placement in surgery. Further, ZBB disclose the claimed invention except for the combination of radiolucent and radiopaque materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct an implant having radiopaque and radiolucent materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims **2, 13, 21-22, 37, 39-41, 43-46, 47-50, 53-55, 57-61, 63** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327.

The combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) disclose the invention described *supra* except for wherein the tissue expander and the spacer may be made at least in part of polyetherketone. Brantigan '327 teaches the use of a preferred polyether ketone in implants (see Col. 3, lines 9-15). It would have been obvious to one having ordinary skill in the art at the time the

Art Unit: 3775

invention was made to construct the device of the combination of Zucherman '342, Brantigan '757 and Branch et al. '592 having at least a tissue expander or spacer made at least partially of polyether ketone in view of Brantigan '327 to be able to view the device and also so that it has optimum biocompatibility once implanted.

Claims **5, 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1 and 19 above, and further in view of Zucherman et al. (US Publication 2001/0012938). The combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) teach the claimed invention except for a spacer having an off-center bore. Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) having at least an off-center bore in view of Zucherman et al. '342 to better orient the spacer in relation to the implant.

Claims **56** is rejected under 35 U.S.C. 103(a) as being unpatentable over the

Art Unit: 3775

combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 as applied to claim 47 and in further view of Zucherman et al. (US Publication 2001/0012938). The combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 teach the claimed invention except for a spacer having an off-center bore. Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 having the off center bore in view of Zucherman et al. (US Publication 2001/0012938) to better orient the spacer in relation to the implant.

Claims **11, 24-25, and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128). Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent

Art Unit: 3775

4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) teach the claimed invention except for an implant resembling specific shapes under X-ray. While the shape under x-ray is generally depending upon the structure of the actual implant, particular placement of radiolucent and radiopaque materials makes the actual structure irrelevant, as these materials control what passes through. Further it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device with either the implant having a certain shape, or placing the opaque/lucent materials strategically to form a particular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of identifying or confirming a location of an implant during surgery or after surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims **38, and 21-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327. Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327. teach the claimed invention except

Art Unit: 3775

for an implant resembling specific shapes under X-ray. While the shape under x-ray is generally depending upon the structure of the actual implant, particular placement of radiolucent and radiopaque materials makes the actual structure irrelevant, as these materials control what passes through. Further it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device with either the implant having a certain shape, or placing the opaque/lucent materials strategically to form a particular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of identifying or confirming a location of an implant during surgery or after surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

Finality

In view of the appeal brief filed on 6/24/2008, PROSECUTION IS HEREBY REOPENED. Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth

Art Unit: 3775

in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733.

Response to Arguments

Applicant's arguments, see appeal brief, filed 6/24/2008, with respect to the rejection(s) of claim(s) 1-41 and 43-67 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection are found above.

Claims under rejection are those submitted on 9/7/2007.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733